


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1172WOORD01		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2004/050377		International filing date (day/month/year) 26.03.2004		Priority date (day/month/year) 28.03.2003
International Patent Classification (IPC) or national classification and IPC A61K31/46, A61K31/44				
Applicant ALTANA PHARMA AG et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 19.10.2004		Date of completion of this report 16.02.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Allnutt, S Telephone No. +49 89 2399-7817		



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

 International application No.
PCT/EP2004/050377

10/550191
Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-11 as originally filed

Claims, Numbers

1-19 as originally filed

Drawings, Sheets

1/4-4/4 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:
 4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/050377

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 9-18

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 9-18 (Industrial applicability)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
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International application No.
PCT/EP2004/050377

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3,11
	No: Claims	1,2,4-10,12-19
Inventive step (IS)	Yes: Claims	
	No: Claims	1-19
Industrial applicability (IA)	Yes: Claims	1-7,19
	No: Claims	9-18

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.
PCT/EP2004/050377

Item III

1. Claims 9-18 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
2. The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

- D1: WO 03/011274 A (GLAXO GROUP LTD ;WARD PETER (GB); KNOWLES RICHARD GRAHAM (GB)) 13 February 2003 (2003-02-13)
- D2: WO 02/069945 A (BOEHRINGER INGELHEIM PHARMA ;PIEPER MICHAEL PAUL (DE); PAIRET MICH) 12 September 2002 (2002-09-12)
- D3: US 2002/052312 A1 (BACH MARK A ET AL) 2 May 2002 (2002-05-02)

The documents considered in the present processing are consecutively numbered D1-D3; this numbering results from the citations D1-D3 found in the Search Report (SR) of the corresponding PCT application. It will be adhered to in the rest of the procedure. The cited passage(s) for each citation will be considered unless otherwise specified.

Item V

Novelty

3. The subject matter of claims 1,2,4-10,12-19 are anticipated by prior art document D1 and therefore do not fulfill the requirements of Art 33(2) PCT.
D1 discloses compositions for treating COPD comprising a PDE4 inhibitor (selection includes riflomilast) which can be administered orally (via pills) and an anticholinergic agent (selected from ipratropium, oxitropium and tiotropium bromide) which can be administered by inhalation.
The free combination compositions can be used in the treatment of pulmonary diseases.
4. The subject matter of claims 3 and 11 are not anticipated by prior art documents D1-D3 and therefore fulfill the requirements of Art 33(2) PCT.

Inventive Step

5. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 3 and 11 do not involve an inventive step in the sense of Article 33(3) PCT.

D1 is considered to be the closest prior art since it discloses free combination compositions comprising a PDE4 inhibitor and an anticholinergic agent for treating respiratory disorders.

The difference of the application with respect to D1 is that the roflumilast is administered intravenously,

It is unclear from the application what special technical effect this route of administration provides over the prior art, since the fact that the combination of the compounds act synergistically, exhibiting a greater than additive effect (pg.2, l.6 and 7) is already known from the prior art (cf. D1-D3).

Therefore it appears that the intravenous route of administration is an obvious alternative providing no real special effect over prior art.

Further Remarks:

Industrial Applicability (Art 33(4) PCT).

6. For the assessment of the present claims 9-18 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.